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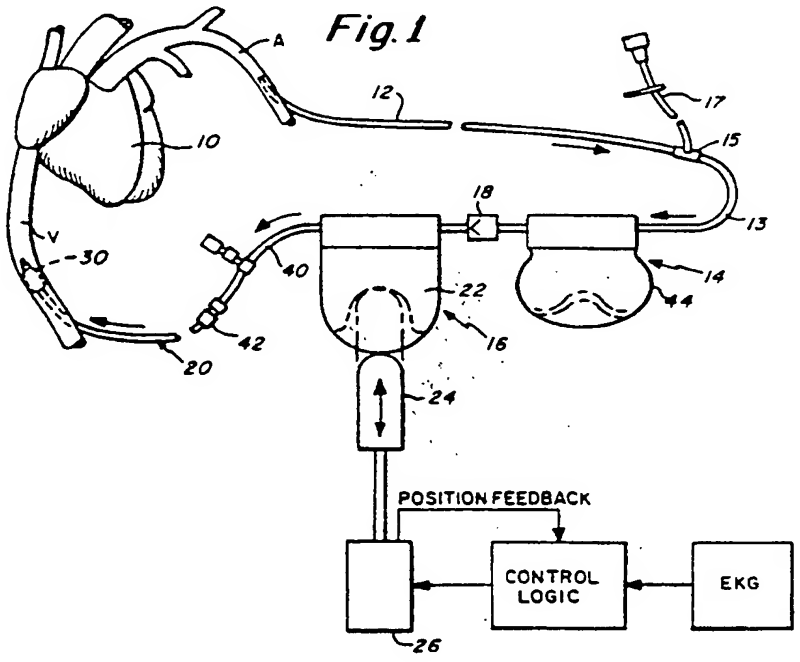
F04B

(54) Blood retroperfusion system

(57) A pump system for use in blood retroperfusion consists of a pump with a variable volume chamber 16 defined by flexible bulb 22, the pump having its outlet connected to a retroperfusion catheter 20 and an inlet connected to a line 12 that receives blood to be retroperfused. A reservoir 14 is provided in the inlet blood flow to the pump. A check valve 18 is provided in the blood flow path between the reservoir 14 and the pump. A reciprocal member 24 operates the pump, and is driven by a moving core, in the form of an electrical coil, in the magnetic field of a permanent or electromagnet.

Fig. 1



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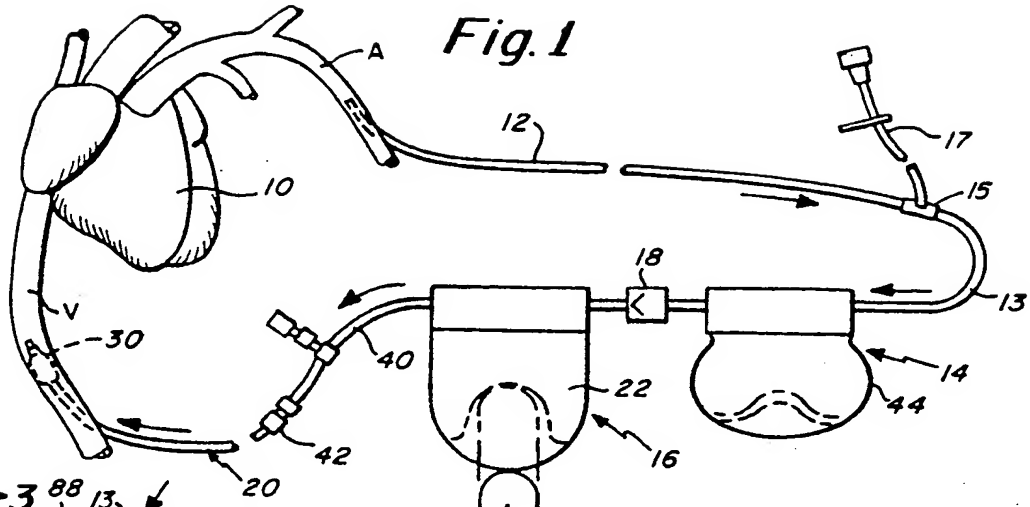


Fig. 1

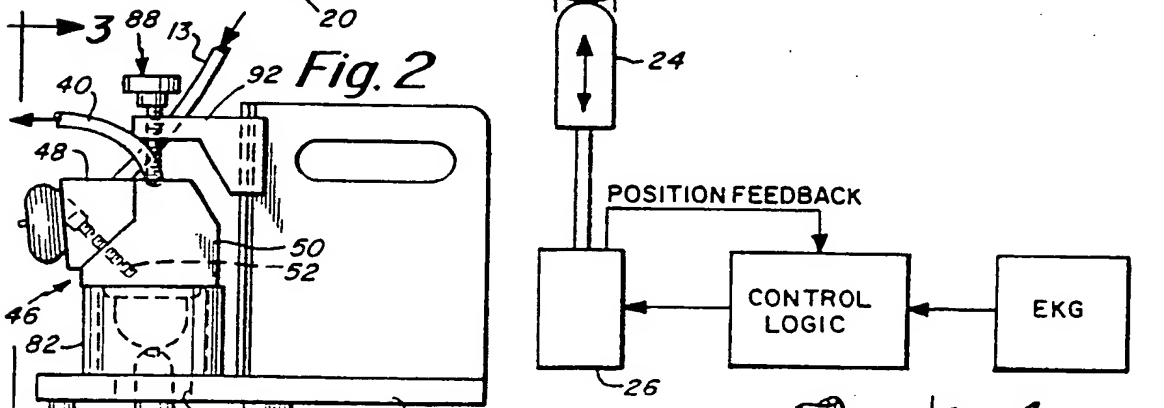


Fig. 2

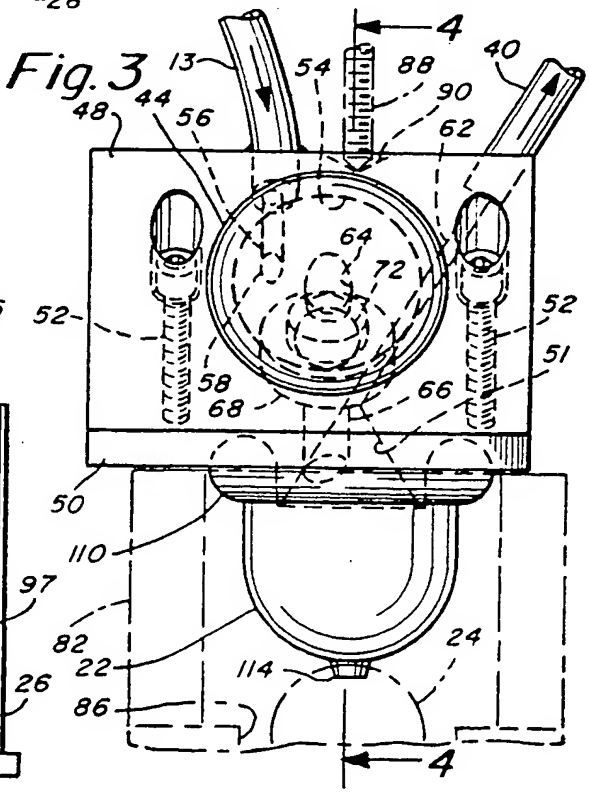


Fig. 3

Fig. 4

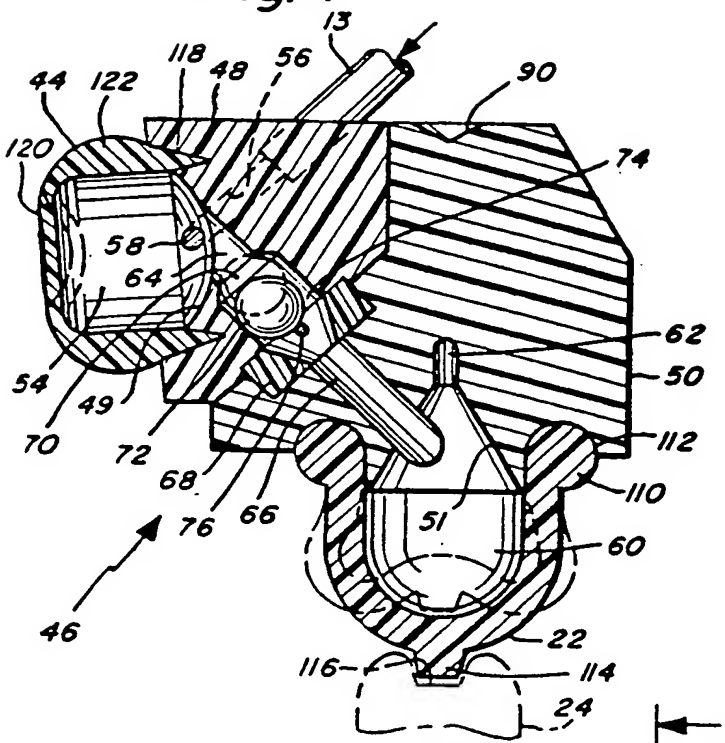


Fig. 5

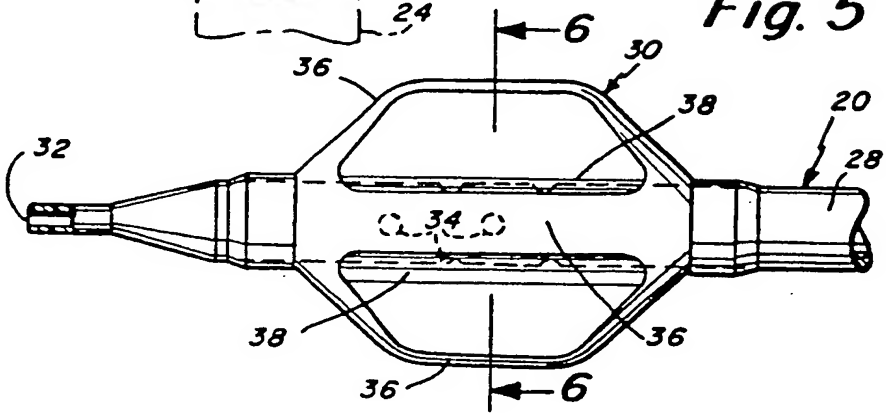
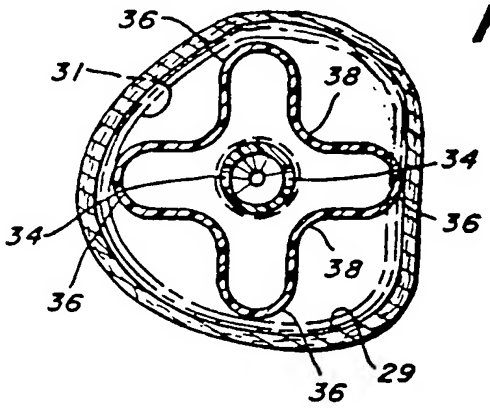


Fig. 6



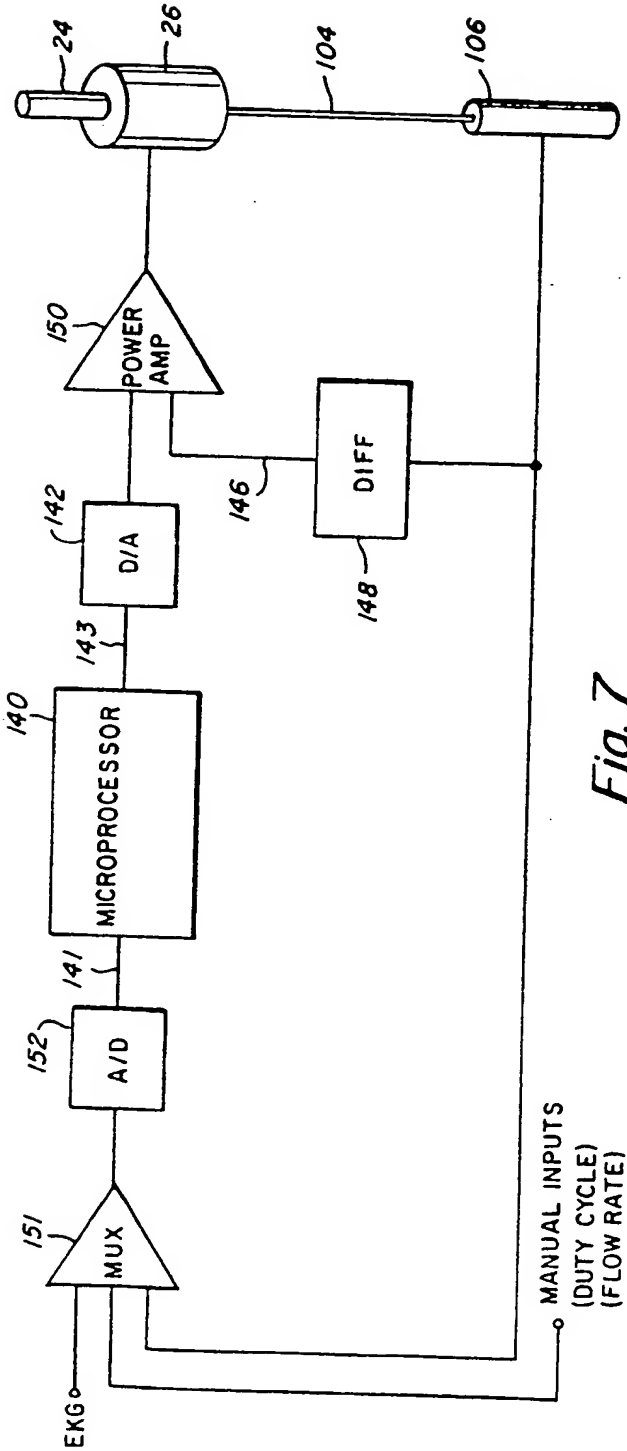


Fig. 7

SPECIFICATION

Blood retroperfusion system

FIELD OF THE INVENTION

This invention concerns a retroperfusion system by which oxygenated blood is shunted from a patient's artery and is supplied through the patient's venous system to a region of a muscle such as the heart, to which the normal arterial blood supply is obstructed.

BACKGROUND OF THE INVENTION

This invention relates to a system for a blood retroperfusion technique in which a temporary supply of oxygenated blood is delivered to a muscle under circumstances in which the normal flow of oxygenated blood cannot reach the muscle through the patient's arteries. For example, blood retroperfusion is a useful procedure when there is a severe blockage in a coronary artery which prevents proper blood flow and nourishment to a portion of the heart muscle. The retroperfusion technique involves shunting temporarily a supply of arterial blood to the undernourished portion of the heart muscle through the coronary vein which leads from the threatened portion of the heart muscle. The technique involves connection of an artery with a vein leading from the endangered portion of the muscle. Blood is pumped from the artery into the vein by a pump which is synchronized with the patient's normal heart rhythm. Each pulse pumps a volume of blood into the vein so that the blood will flow in a retrograde direction, opposite to the normal flow direction in the vein, and may reach the endangered portion of the muscle. Each pulse of the pump pumps blood to the muscle during the diastolic phase of the patient's heart rhythm. During the systolic phase of the patient's heart rhythm, the retroperfused blood is permitted to reverse its direction and flow through the vein, in a normal flow direction away from the muscle.

A special type of balloon catheter is used in the retroperfusion technique. Such a catheter is described in U.S. patent 4,290,428 which describes an inflatable and a deflatable balloon attached to the distal end of the catheter which is to be inserted into the vein. The balloon is constructed to form a temporary seal between the catheter and the lumen of the vein. The seal prevents blood from draining while the blood is infused during the diastolic pulse. The inflated balloon assures that the maximum volume of oxygenated blood can flow through the vein to the muscle during diastole. The balloon catheter also is constructed so that the balloon seal will collapse after the diastolic pulse to permit the blood to reverse its flow within the vein and drain from the muscle. The seal should be made and broken in phase with the systolic-diastolic rhythm of the patient's pulse.

The procedure and apparatus which may be used in the procedure is described generally in Farcot, *Synchronized Retroperfusion of Coronary Veins for Circulatory Support of Jeopardized Ischemic Myocardium*, The American Journal of Cardiology, June 1978, pp. 1191-1201.

The retroperfusion technique is usable in numerous situations in which the supply of oxygenated blood to the heart muscle is obstructed. This may occur in any arterial location in the body although it presents a particularly critical situation when the obstruction is in the coronary arteries which supply oxygenated blood to the heart muscle itself. Thus, the retroperfusion procedure may be of critical importance in maintaining a supply of oxygenated blood to the heart muscle during those critical moments leading to a potential myocardial infarction (heart attack). The retroperfusion technique, may be administered quickly to maintain alive the threatened portion of the muscle until the patient can be taken to and/or made ready for further treatment.

In addition to its use as an emergency lifesaving technique as described above, the retroperfusion technique also is usable during certain kinds of treatment for arterial obstructions. In recent years another technique known as angioplasty has developed in which a different type of balloon catheter is inserted into the blocked artery and is positioned with its balloon within the narrowed or blocked region. The balloon then is inflated to cause the blocking plaque in the artery to be compressed radially and outwardly against the wall of the artery thereby enlarging the internal bore in the artery. The angioplasty technique has been used in numerous instances as an alternative to more extensive coronary bypass surgery. During the angioplasty procedure, however, the inflation of the angioplasty balloon itself blocks the artery and prevents all flow of blood to the location downstream of the stenosis being treated. Because a complete cutoff of blood flow is itself a threat to the muscle located downstream of the arterial blockage, the angioplasty technique requires that the balloon be inflated only for relatively short periods of time. By the simultaneous use of retroperfusion, however, oxygenated blood may be supplied to the portions of the muscle which otherwise would be blocked by the angioplasty balloon. Thus, by concurrent use of retroperfusion and angioplasty techniques, the angioplasty procedure may continue for longer periods of time than previously were permitted thereby enabling more complete and better treatment of the lesion by angioplasty than was previously attainable.

The retroperfusion techniques proposed thus far have not been without some risk. Very careful control must be maintained over the pressure which builds up in the patient's circu-

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latory system as a result of use of the retroperfusion balloon. If the pressure is permitted to build up to too high a level, hemorrhaging and other difficulties can result. Another difficulty with the retroperfusion systems proposed in the art has been that the pump systems for synchronizing and controlling operation of the catheter have been of inefficient design and function.

It is among the general objects of the present invention to provide an improved pump system for a blood retroperfusion technique.

SUMMARY OF THE INVENTION

The present invention may be used with a catheter having a main body, a lumen and a distally located balloon. The lumen extends fully through the catheter, from the proximal end to the distal tip, and is open at the distal tip. The lumen is intended to receive oxygenated blood at its proximal end and deliver that blood to the distal end. The lumen is in communication with the interior of the balloon by a plurality of holes which are formed in the catheter body within the balloon region. The cross-sectional flow area of the holes communicating with the inside of the balloon is larger than the outlet of the lumen at the distal tip of the catheter so that there is greater resistance to flow through the outlet at the distal tip than there is through the apertures into the balloon. During diastole, when blood is pumped through the catheter it will fill and inflate the balloon to expand it to a sealed configuration against the lumen of the vein before any substantial blood flows out of the distal outlet. When blood begins to flow through the distal outlet into the vein the balloon will already have been expanded and will be sealed in place thereby assuring that all of the pulsed blood will flow in a retrograde direction toward the portion of the muscle to be nourished. When the pulse has terminated and systole begins, the drop in pressure within the catheter enables the blood within the balloon to drain quickly through the relatively large openings in the catheter thereby unblocking the vein and permitting the blood to drain through the vein.

The improved pumping system of the present invention includes a pump having an outlet which is connected to the proximal end of the lumen in the retroperfusion catheter. The inlet end of the pump is connected by another catheter to the source of oxygenated blood, such as the patient's artery. The pump, which is constructed to pump pulses of blood through the retroperfusion catheter, is driven in phase with the patient's cardiac rhythm so that a pulse of blood will be pumped at the desired time during diastole.

The pump includes a main chamber which is defined in part by a resilient compressible bulb, the main chamber having an outlet which is connected to the retroperfusion catheter. The main chamber is filled with blood through a one-way inlet port. Compression of the bulb forces blood which was within the main chamber to be pumped through the retroperfusion catheter while simultaneously shutting off a check valve in the one-way inlet port. When the compressible bulb is relaxed, its inherent resilience causes it to expand toward its relaxed configuration thereby returning the pump chamber to its normal volume. That action creates a reduced pressure within the pump chamber which opens the check valve and permits blood to be drawn into the chamber from a reservoir in readiness for the next pumping stroke. It also draws back some of the blood from the retroperfusion catheter which accelerates collapse of the balloon.

The pump includes a reservoir chamber which feeds the main chamber through the one-way check valve. The reservoir chamber is connected to a catheter leading from the patient's artery. The reservoir chamber is maintained under a slight negative pressure by a resilient bulb which, during operation of the pump, is always compressed, the degree of compression oscillating as the pump operates. The slightly negative pressure in the reservoir aids in drawing arterial blood from the patient. The reservoir bulb is more resilient and flexible than the compressible bulb of the pump main chamber so that flexure of the stiffer compressible bulb in the main chamber can control and override the inherent resilience of the more flexible bulb in the reservoir chamber. That results in an action in which the reservoir bulb oscillates between a partially and a more fully collapsed position and, maintains a negative pressure in the reservoir and on the arterial catheter at all times.

The invention also includes a control system for operation of a linear motor which drives the main bulb. The system includes an input of the patient's electrocardiogram as well as an input from a linear motion detector which is connected to and monitors the position and motion of the linear motor. Control means are provided to enable the operator of the system to adjust the timed operation between the pump system and the patient's heart rhythm as well as to vary and control the various parameters of the pump operations such as frequency of pumping, volume pump per stroke and speed of stroke.

It is among the general objects of the invention to provide an improved blood retroperfusion system.

Another object of the invention is to provide a retroperfusion system including a pump and retroperfusion catheter which cooperate to provide a rapid inflation and deflation response.

Another object of the invention is to provide a retroperfusion system in which the pump is self-filling and maintains a constant draw of blood supply from the patient's arterial sys-

tem.

A further object of the invention is to provide a retroperfusion pump which has a low level of blood turbulence.

Another object of the invention is to provide a blood retroperfusion pump having two chambers in which pressure variations in one of the chambers drive the other chamber.

A further object of the invention is to provide a retroperfusion pump which, in addition to drawing blood from the patient's artery, also draws from the retroperfusion catheter to accelerate balloon collapse.

Another object of the invention is to provide a retroperfusion pump system in which portions of the pump are formed from inexpensive disposable materials thereby avoiding the need for sterilization for reuse and also avoiding the potential risk from incomplete sterilization.

Still another object of the invention is to provide a pump system of the type described in which the disposable portion of the pump is quickly and easily detached from the pump drive mechanism.

DESCRIPTION OF THE DRAWINGS

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying drawings wherein:

FIG. 1 is a diagrammatic illustration of the retroperfusion system, illustrating the manner in which it is connected across the patient's arterio-venous system;

FIG. 2 is a side elevation of the pump system;

FIG. 3 is a front elevation of the detachable pump module as seen from a position indicated at 3-3 in FIG. 2;

FIG. 4 is a sectional elevation of the pump module as seen along the line 4-4 in FIG. 3;

FIG. 5 is an enlarged side elevation of the distal end of the retroperfusion catheter illustrating the balloon;

FIG. 6 is a sectional illustration of the retroperfusion catheter as seen along the line 6-6 of FIG. 5 and illustrating the manner in which the balloon collapses within the vein; and

FIG. 7 illustrates the control circuitry for the system.

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 illustrates the manner in which the retroperfusion system may be connected to deliver oxygenated blood from the patient's arterial system to a vein leading to the threatened portion of a muscle, such as the great cardiac vein which leads from the left ventricle of the patient's heart 10. The system includes an arterial catheter indicated generally at 12 which may be introduced through the patient's femoral artery and advanced to the descending aorta. The arterial catheter 12 communicates with a reservoir chamber 14 which, in turn, feeds a pump chamber indicated generally at 16, through a check valve 18. The outlet from the pump chamber 16 is connected to a retroperfusion catheter, indicated generally at 20 which is placed in the selected vein of the patient so as to be in a position to deliver oxygenated arterial blood to that portion of the muscle, such as the heart, which is threatened and requires treatment. As will be described in greater detail below, the system draws arterial blood through the catheter 12, stores it briefly in the reservoir chamber 14, transfers the blood to the pump chamber 16 from which it is pumped, in periodic pulses, through the retroperfusion catheter 20 and into the patient's vein V. The pump chamber 16 includes a flexible bulb 22 which is alternately compressed and relaxed by a plunger 24 which engages the bulb 22 and is movable toward and away from the bulb alternately to compress the bulb in a pumping stroke and then to relax the bulb in a filling stroke. The plunger 24 is driven by a linear reciprocable motor 26 which is controlled in its timing, speed and stroke.

As shown in FIG. 5, the retroperfusion catheter 20 includes a tubular body 28 having an automatically inflatable and deflatable balloon 30 attached to the distal end of the body 28. The balloon is constructed so that when blood is pumped through the catheter, the blood first will fill and inflate the balloon 30. The balloon inflates against the surface of the lumen 29 of the vein as suggested in phantom at 31 in FIG. 6 to form a temporary seal between the balloon and the vein during the pumping stroke. The pumping stroke is timed to occur during the diastolic phase of the patient's heart rhythm to maximize the retrograde flow of blood to the heart muscle. The balloon is constructed so that it will collapse after the retrograde infusion of oxygenated blood has been completed thereby to permit the blood to reverse its flow and drain from the myocardium. It is important that the seal between the balloon and the vein be made and broken in the desired phase with respect to the patient's heart rhythm.

The catheter has an outlet port 32 at its distal tip. The balloon 30 is mounted on the catheter body 28 proximally of the distal tip. The portion of the catheter body 28 which is contained within the balloon 30 is provided with a number of apertures 34 which have an aggregate cross-sectional area opening into the balloon which is larger than the cross-sectional area of the outlet port 32. The larger cross-sectional flow area into the balloon 30 than at the outlet port 32 results in a greater flow resistance through the distal outlet than through the intra-balloon apertures. During an infusion pulse, blood pumped through the catheter first will tend to fill and inflate the

balloon 30 to expand it into a sealed configuration against the lumen of the vein (as indicated in phantom at 31 in FIG. 6) before any substantial blood flows out of the distal outlet port 32. When blood begins to flow through the distal outlet port 32, the balloon will already have been expanded and will be sealed in place thereby maximizing the amount of pulsed oxygenated blood that will flow in a retrograde fashion toward the portion of the muscle to be treated. When the pumping pulse terminates, the drop in blood pressure within the catheter enables the blood within the balloon to drain quickly through the relatively large intra-balloon apertures 32 thereby collapsing the balloon.

The balloon is constructed so that it will collapse along longitudinally extending fold lines so that it appears to be somewhat of a star-shaped pattern when viewed from the end of the catheter, as illustrated in FIGS. 5 and 6. The star or lobular cross-sectional configuration defined by the balloon results in a plurality of alternating lobes 36 and channels 38. The channels 38 define a plurality of substantial cross-sectional flow areas to enable blood to drain quickly from the retroperfused site. The balloon preferably is formed from vinyl or latex in a dip forming process on a forming mandrel having the somewhat star-shaped configuration which the balloon desirably will assume when collapsed. After the balloon material has cured on the mandrel and has been peeled off it will tend to assume the star-shaped collapsed configuration and is inherently biased in that shape.

The retroperfusion catheter 20 is connected, at its proximal end, to the outlet conduit 40 from the pump chamber 16, as by a Luer-Lok connector 42 fitted to the distal end of the conduit 40 and proximal end of retroperfusion catheter 20. The pump chamber 16 is filled with blood through a one-way inlet port which is defined by the check valve 18. When the resilient compressible bulb 22 which forms part of the pump chamber 16 is compressed by a stroke of the plunger 24, blood which was within the pump chamber 16 is pumped through the retroperfusion catheter while simultaneously shutting off the check valve 18 in the one-way inlet port. During the pumping stroke the balloon 30 inflates to form a seal against the lumen of the vein, as described above, and thereafter, the oxygenated blood is pumped out of the distal outlet port 32. When the compressible bulb 22 is released, by retraction of the plunger 24, the inherent resilience of the bulb 22 causes it to expand toward its relaxed configuration thereby returning the pump chamber 16 toward its normal volume. That action creates a reduced pressure within the pump chamber 16 which opens the one-way check valve 18 and permits blood to be drawn into the pump chamber from the reservoir chamber 14 to prime the pump chamber 16 in readiness for the next pumping stroke. The reduced pressure developed by the expanding action of the flexible bulb 22 also draws back some of the blood from the retroperfusion catheter 20 which accelerates collapse of the balloon 30.

The reservoir chamber 14 feeds the pump chamber 16 through the one-way check valve 18. The reservoir chamber 14 is connected by an inlet conduit 13 to the arterial catheter 12 which leads from the patient's artery. The inlet conduit 13 preferably is permanently attached to the reservoir chamber and is provided with a Luer fitting 15 at its proximal end which is connectable with a mating Luer fitting at the proximal end of the arterial catheter 12. The Luer fitting 15 may be provided with a side port 17 to provide communication with the arterial blood flow upstream of the reservoir chamber 14. The arterial catheter 12 may be selected from any of a variety of commercially available catheters usable for arterial communication. The reservoir chamber 14 also is defined in part by a flexible resilient bulb 44. The reservoir chamber 14 is maintained under a slight negative pressure by the reservoir bulb 44 which, during operation of the pump, is always compressed. The degree of compression of the reservoir bulb 44 oscillates as the pump operates. The slightly negative pressure in the reservoir chamber 14 aids in drawing arterial blood from the patient.

The reservoir bulb 44 is more flexible and resilient than the compressible bulb 22 of the pump chamber 16. When the pump chamber bulb 22 is compressed by the plunger 24 the check valve 18 closes. The natural resilience of the reservoir bulb 44 then causes it to expand toward its normally extended configuration which draws arterial blood into the reservoir chamber 14. As will be described, the timing of the system is such that before the reservoir bulb 44 expands fully, the plunger 24 will have been retracted, thereby releasing the stiffer compressible pump chamber bulb 22. The stiffer pump chamber bulb 22 expands with a greater force than that which is developed by the more flexible, weaker reservoir bulb 44. Thus, as the pump chamber bulb 22 expands to draw oxygenated blood from the reservoir, the reduced pressure developed by the expanding pump chamber bulb 22 overcomes the expanding force of the reservoir bulb 44. As a result, when the pump chamber bulb 22 expands, it creates enough suction to cause the reservoir bulb 44 to partially collapse. As the plunger 24 alternately compresses and releases the pump chamber bulb 22, the reservoir bulb 44 oscillates between a partially and a more fully collapsed position. The effect is to maintain a negative pressure in the reservoir and, therefore, on the arterial catheter at all times.

FIGS. 2, 3 and 4 show an illustrative embodiment of the system in which the reservoir

14 and pump 16 are formed in a pump module, indicated generally at 46. The pump module 46 is detachably mounted to the system for driving the pump so that after a procedure has been completed the blood contacting portions of the system, including the arterial catheter 12, pump module 46 and retroperfusion catheter 20 may be disposed of as a unit and may be replaced with a new sterile module 46 and catheters 12, 20.

The module 46 preferably is made from plastic and may be molded or machined. In the illustrative embodiment, the module 46 is molded from a pair of sections including a reservoir section 48 and a pump section 50. The sections 48, 50 are secured together as by screws 52. The reservoir bulb 44 is mounted to the reservoir section 48 of the module 46 and cooperates with the module to define the reservoir chamber 54. The reservoir section 48 may be provided with a cavity 49 which defines a portion of the reservoir chamber 54. An inlet conduit 56 is formed through the reservoir section 48 and communicates, in an inlet port 58 with the reservoir chamber 54. The inlet conduit 56 is in communication with the conduit which is securely connected, as by adhesive, to the module section 48.

The pump bulb 22 is mounted to the pump section 50 and cooperates with the pump section 50 to define the pump chamber 60. The pump chamber 60 also may be defined in part by a cavity, such as the conically shaped cavity 51 formed in the pump section 50 and which defines a portion of the pump chamber 60. The pump chamber 60 communicates by an outlet passage 62, formed in the pump section 50, with the pump outlet 40.

The reservoir chamber 54 and pump chamber 60 are connected by an internal passageway 64, 66 to permit blood to flow from the reservoir chamber 54 to the pump chamber 60. In the illustrative embodiment a seal 68 is provided at the juncture of the passageway segments 64, 66, where the reservoir and pump sections 48, 50 meet. The check valve 18 is formed along the passageway 64, 66 to permit flow only from the reservoir to the chamber 54 to the pump chamber 60. In the illustrative embodiment the check valve 18 is formed by providing a valve seat 70 in the passageway 64. A freely movable ball 72 is contained within an enlarged valve chamber 74 formed in the passageway 64. The ball 72 is retained within the ball chamber 74, so as not to obstruct the passage 66, by a transverse pin 76 which is secured to the sealing ring 68 and extends across the opening in the sealing ring. From the foregoing it will be appreciated that when pressure is applied to the pumping chamber 60 the ball 72 will be forced against the valve seat 70, as illustrated in phantom in FIG. 4, to prevent flow from the pump chamber 60 to the reservoir 54. When the pressure in the pump chamber 60 is reduced, as when plunger 24 is retracted, the ball 72 will shift to the open position shown in solid in FIG. 4 to permit flow from the reservoir chamber 54 to the pump chamber 60.

FIGS. 2 and 3 illustrate the manner in which the pump module 46 is mounted for operation in accordance with the invention. The system includes a frame 78 which supports a platform 80. A module holder 82 is supported on the platform 80 and provides support for the module 82. The module holder 82 is in the form of a hollow ring. The holder 82 is located on the platform 80 in registry with an aperture 86 in the platform 80. The module holder 82 is arranged with respect to the aperture 86 and the plunger 24 so that the plunger can extend upwardly through the registered aperture 86 and ring to engage the flexible pump bulb 22. The module 46 is held securely in place on the holder 82 by a clamp 88. In the illustrative embodiment the clamp 88 is in the form of a screw which can be tightened down to engage the upper surface of the module 46. The upper surface of the module may be provided with an indentation 90 which provides a secure engagement for the end of the clamping screw 88. The clamping screw 88 may be supported by an appropriate bracket 92 secured to the frame 78.

The system includes a linear motor 26 which is mounted conveniently to the frame 78. The motor 26 has an output rod 94 which reciprocates vertically. The output rod 94 is connected to a moving core 95 which consists of an electrical coil. The coil resides in a magnetic field established by the stator portion 97 which may consist of permanent magnets or an electrode magnet. Current passing through the coil in the core 95 interacts with the magnetic field established by stator 97 in a manner similar to that of the voice coil in a speaker to cause motion of the output rod 94. Motor 26 is designed so that movement of rod 94 is proportional to the voltage applied to the coil of the core 95. The design and construction of the linear motor such as motor 26 is well known and will not be described further in detail. However, the control circuit which operates on motor 26 will be described hereinafter.

The output rod 94 is pinned at 96 to a drive link 98 which is pivoted, at its other end with respect to the platform 80, at pivot pin 100. The plunger 24 is pivotally connected to the drive link 98 at pivot 102. Connected to and extending downwardly from the plunger 24 is a connecting rod 104, the lower end of which is connected to a linear position transducer 106. A transducer 106 is secured to a frame as by a bracket 108. The transducer 106 senses the vertical position of the rod 104 and plunger 24, thereby providing an indication of the degree to which the bulb 22 has been compressed, and also provides for

stabilization of the lower end of the rod 104.

Both of the bulbs 22, 24 are formed from a biologically inert material such as appropriate silicone rubber compound. The pump chamber bulb 22 is generally cylindrical with a hemispherical closed end. The open end of the bulb may be provided with an enlarged bead 110 which seats within an annular channel 112 and provides a substantial area along which the bead 110 may be bonded to the module 46, as by suitable adhesive. The wall thickness of the bulb 22 is substantially uniform and is relatively thick as compared to the reservoir bulb 44, described below. The shape and size of the bulb 22 coupled with the size of the plunger 24 provides a rolling cuff mode of operation, as suggested in phantom in FIG. 4 which assures that there will be no rubbing or abrasion of the inner surface of the bulb 22 as it expands or collapses thereby avoiding the chance that a particle of bulb material might wear loose and be carried away in the blood stream. The diameter of the plunger 24 should be selected with respect to the inner diameter of the pump bulb 22 to provide the rolling cuff operation. If the plunger 24 is too large, undesirable abrasion may result. The bottom of the bulb 22 may be molded to include a boss 114 on its end which may be engaged by a socket 116 formed at the upper end of the plunger 24.

The reservoir bulb 44 also is formed from suitable silicone rubber and is fitted into a complimentary shaped groove 118 where it is adhesively attached to the module 46. The reservoir bulb 44 may have the tapered mating shape shown or may be provided with a beaded configuration similar to that of the pump chamber bulb 22. The reservoir bulb 44 also is generally cylindrical except that its bottom wall 120 is relatively flat and thin and its side wall 122 is thicker than the bottom wall 120. When the reservoir bulb 44 collapses it will do so in a controlled manner in the relatively thin bottom wall 120.

FIG. 7 illustrates the control circuit by which operation of motor 26 may be controlled to provide the desired retroperfusion action. As shown, the control system includes a microprocessor 140 which illustratively may be a well-known commercial processing device such as a model 8096 manufactured by Intel Corporation of San Diego, California. Such a microprocessor typically has an input bus, 141, which receives information in the form of digital words. Information received over input bus 141 can be transferred to an internal memory and processed by arithmetic logic (not shown). The microprocessor can generate information in the form of digital words on an output bus, 143.

Connected to input buss 141 is an analog/-digital converter 152 which converts various analog inputs into the digital words necessary to control microprocessor 140. The analog signal input to A/D convertor 152 is, in turn, supplied by multiplexor 151. Multiplexor 151 has three different analog inputs which can be selectively connected to convertor 152 under control of signals generated by microprocessor 140.

One analog input includes synchronization signals provided from well-known equipment (not shown) which monitors the patient's electrocardiogram signals and/or blood pressure. During the operation of the instant retroperfusion system, these latter signals synchronize the operation of retroperfusion pump to the patient's natural systolic/diastolic cardiac rhythm.

Another input provided to multiplexor 151 are signals provided from a set of manual switches or potentiometers, which signals establish the desired duty cycle for operation of motor 26 as well as the desired blood flow rate (flow rate is a function of the velocity of the motor actuator 24).

During operation, microprocessor 140 also receives a third analog position feedback signal from linear position transducer 106 which is connected, via rod 104, to actuator rod 24 of motor 26. The position signal is provided to microprocessor 140 so that microprocessor 140 can sense when rod 24 reaches the desired limit of travel.

In response to the input signals, microprocessor 140 produces a digital output signal and this signal is converted into a analog signal by digital/analog convertor 142. The resulting analog signal is representative of a desired velocity of motor actuator rod 24 corresponding to a desired flow rate at a given point in the patient's systolic/diastolic rhythm.

The analog velocity signal is provided to one input of a differential power amplifier, 150, the output of which drives motor 26. The other input of the differential power amplifier 150 is provided with the output of a differentiator 148, via lead 146. Differentiator 148 differentiates the position signal produced by transducer 106 and, thus, provides a feedback signal which is equivalent to the actual velocity of the actuator rod 24.

By means of the differential input of amplifier 150, a signal equivalent to the difference of the desired velocity signal (generated by convertor 142) and the actual velocity signal (generated by differentiator 148) is applied to motor 26 to control its velocity. This control arrangement is a standard control arrangment and controls motor 26 to impart a constant velocity to the actuator rod 24.

Therefore, in accordance with the control circuit operation, microprocessor 140 advances motor actuating rod 24 at a constant velocity until the actuator rod reaches the desired end of its travel which condition is sensed by microprocessor 140 by means of the position signal provided to its input. At this time, microprocessor 140 reverses the

sign of the velocity signal causing rod 24 to return in the opposite direction until the opposite endpoint is reached. Repetition of this action results in an oscillation of actuator rod 24 to produce the desired retroperfusion action.

It should be understood that the foregoing description of the invention in intended merely to be illustrative thereof and that other embodiments and modifications may be apparent to those skilled in the art without departing from its spirit.

Having thus described the invention what we desire to claim and secure by letters patent is:

CLAIMS

1. A pump system for use in blood retroperfusion comprising:

a pump chamber having a variable volume defined at least in part by a flexible resilient member, said pump chamber having an outlet connectable to a retroperfusion catheter and an inlet adapted to receive blood to be retroperfused;

a reservoir chamber having an inlet connectable to receive blood to be retroperfused and an inlet to the pump chamber thereby to define a flow path from the inlet of the reservoir chamber to the outlet of the pump chamber;

check valve means for permitting flow from the reservoir chamber to the pump chamber and for preventing flow from the pump chamber to the reservoir chamber;

means for expanding and contracting the volume of the pump chamber thereby to pump blood through the outlet of the pump chamber when the volume of the pump chamber is contracted and to fill the pump chamber with blood from the reservoir chamber when the volume of the pump chamber is expanded.

2. A pump as defined in claim 1 further comprising:

means for maintaining the reservoir chamber under a negative pressure at least during a portion of the cycle of operation of the pump to assist filling the reservoir chamber through the inlet.

3. A pump as defined in claim 2 further comprising:

said reservoir chamber being formed in part from a flexible resilient member, said reservoir chamber being contractible in response to expansion of the pump chamber in a filling stroke.

4. A pump as defined in claim 2 further comprising:

means for maintaining said reservoir chamber under a negative pressure at all times during the cycle of operation of the pump to draw blood continually into the reservoir chamber.

5. A pump as defined in claim 1 further comprising:

said pump chamber being formed at least in a part by a flexible resilient member constructed and arranged to expand under its own resilience.

6. A pump as defined in claim 5 further comprising:

said reservoir chamber being defined at least in part by a flexible resilient member;

a flexible resilient member of the pump chamber being stiffer than the flexible resilient member of the reservoir chamber so as to cause said reservoir chamber to contract when the volume of the pump chamber expands.

7. A pump as defined in claim 5 further comprising:

means for alternately compressing and releasing the flexible member of the pump chamber.

8. A pump as defined in claim 7 wherein the means for alternately compressing and releasing the pump chamber comprises:

an actuator moveable toward and away from the flexible member of the pump chamber; and

drive means for moving the actuator toward and away from the pump chamber.

9. A pump as defined in claim 7 further comprising:

a housing;

said pump and reservoir chambers being defined at least in part by said housing;

a frame for detachably supporting the housing in a predetermined position with respect to said means for alternately compressing and releasing the pump chamber.

10. A pump as defined in claim 6 further comprising:

said resilient member of the pump chamber being formed from an elastomeric material having a cylindrical portion and a hemispherical portion continuous with an end of the cylindrical portion and having a substantially uniform wall thickness;

said resilient flexible member of said reservoir chamber being formed from an elastomeric material and having at least a portion thereof which is thinner and more flexible than the flexible resilient member of the pump chamber.

11. A pump as defined in claim 10 wherein the reservoir flexible resilient member further comprises:

a cylindrical member having an end wall, the cylindrical portion of the member being relatively thick and the end wall being relatively thin, the end wall defining the most flexible portion of the member.

12. A pump as defined in claim 5 further comprising:

a retroperfusion catheter connected to the outlet of the pump chamber and an arterial catheter connected to the inlet to the reservoir chamber.

13. A pump as defined in claim 9 further comprising:

said housing having a cavity formed therein to define in part the pump chamber;

the remainder of said pump chamber being defined by the flexible resilient bulb, said bulb being attached to the housing over the first cavity;

said housing having a second cavity which defines in part the reservoir chamber;

the flexible resilient member of the reservoir chamber being defined by a flexible resilient bulb mounted to the housing over the second cavity;

conduit means extending through the housing communicating the first and second cavities;

said check valve means being disposed in the internal housing conduit.

14. A disposable module for a retroperfusion pump comprising:

a housing;

a pair of chambers defined on said housing, said chambers including a pump chamber and a reservoir chamber, each of said chambers being defined at least in part by a flexible resilient member;

means on the housing for defining an inlet to the reservoir chamber;

means on the housing for defining an outlet from the pump chamber;

conduit means extending through the housing and communicating said chambers; and

check valve means within the conduit for permitting one way flow from the reservoir chamber to the pump chamber.

15. A disposable module as defined in claim 14 further comprising:

a retroperfusion catheter connected to the outlet of the pump chamber; and

an arterial catheter connected to the inlet of the reservoir chamber.

16. A module as defined in claim 14 wherein said flexible resilient members of said pump chamber and said reservoir chamber comprise bulbs mounted to the housing.

17. A pump module as defined in claim 16 wherein the pump chamber bulb is constructed and arranged as to curl without internal rubbing contact of the walls of the bulb when the bulb is depressed by an actuator, said pump bulb being shaped in a cylindrical form having a hemispherical end and a uniform wall thickness at each of said cylindrical and hemispherical portions.

18. A pump module as defined in claim 17 wherein the reservoir bulb has relatively thick side walls and a thin flexible bottom wall, the thin flexible bottom wall being thinner than the wall on the pump chamber bulb.

19. A method for actuating a retroperfusion catheter, said catheter having a main shaft with a lumen extending therethrough, the lumen terminating at the distal end of the shaft in an outlet, a retroperfusion balloon mounted to the distal region of the shaft, the shaft having flow openings communicating the shaft lumen to the interior of the retroperfusion balloon, the flow area defined by the openings into the balloon being greater than the flow area defined at the distal outlet of the catheter, said method comprising:

applying a pulse of blood through the catheter under a positive pressure for a predetermined time sufficient to cause the retroperfusion balloon to inflate and to cause a volume of blood to be ejected from the distal outlet from the catheter;

terminating said positive pressure pulse and applying a pulse of negative pressure to the lumen to accelerate collapse of the retroperfusion balloon.

20. A pump system for use in blood retroperfusion substantially as hereinbefore described with reference to the accompanying drawings.

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